IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

SIGHT SCIENCES, INC.,	
)	C. A. No.: 21-1317-GBW-SRF
Plaintiff,	
)	JURY TRIAL DEMANDED
v.)	
)	
IVANTIS, INC., ALCON RESEARCH LLC,)	
ALCON VISION, LLC AND ALCON INC.,	
	Redacted - Public Version Filed on:
Defendants.	November 14, 2023

CONCISE STATEMENT OF ADDITIONAL FACTS IN SUPPORT OF SIGHT SCIENCES, INC.'S OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT NO. 1 OF INVALIDITY FOR LACK OF ENABLEMENT

YOUNG CONAWAY STARGATT & TAYLOR, LLP
Melanie K. Sharp (No. 2501)
James L. Higgins (No. 5021)
Taylor E. Hallowell (No. 6815)
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
msharp@ycst.com
jhiggins@ycst.com
thallowell@ycst.com

COOLEY LLP Michelle S. Rhyu Jeffrey Karr Lauren Strosnick Alissa Wood Juan Pablo González Angela R. Madrigal 3175 Hanover Street Palo Alto, CA 94304-1130 (650) 843-5000

Orion Armon 1144 15th Street, Suite 2300 Denver, CO 80202-2686 (720) 566-4000

Dustin M. Knight Joseph Van Tassel Reston Town Center 11951 Freedom Drive, 14th Floor Reston, VA 20190-5656 (703) 456-8000

Bonnie Fletcher Price 1299 Pennsylvania Avenue, NW, Suite 700 Washington, DC 20004-2400 (202) 842-7800

Attorneys for Sight Sciences, Inc.

Dated: November 2, 2023

- 1. The Asserted Claims containing one of the limitations that Defendants collectively refer to as the "Block Limitation" (see D.I. 300 (DSOF1) ¶2) include structural limitations that limit the scope of the claims and serve to guide a POSA on how to achieve the "does not significantly block" flow limitation. (See Ex. 90 (Downs Reb.) ¶¶1064-1066, 1082-1093; Ex. 93 (Downs 9/28 Tr.) 35:7-25, 89:7-15.) For example, the Asserted Claims recite the following: (a) a "support" structure that props open Schlemm's canal (all Asserted Claims); (b) support includes an "arcuate member" (all Asserted Claims of '443, '361, '742, & '328); (c) arcuate member has a radius of curvature smaller than that of Schlemm's canal (all Asserted Claims of '443, '361, '742, & '328); (d) the arcuate member extends out of Schlemm's canal (all Asserted Claims of '443, '742, & '328; '361, cl. 9); (e) support **contacts less than 30%** of internal wall surface area (all Asserted Claims of '443 and '482; '742, cl 13; '328, cl. 21); (f) support has at least one fenestration (all Asserted Claims of the '482 & '361; '443, cl. 8; '742, cl. 2; '328, cls. 22-23); (g) support has a circumference equal to about a [half/quarter] or less than the circumference of Schlemm's canal ('443, cls. 11-12; '742, cl. 3; '328, cl. 18); (h) **discontinuous or periodic contact** along a perimeter of the lumen of the canal ('482, cls. 7, 38, 69); (i) support has fluted edges ('482, cls. 5, 36, 68), among others.
- 2. The Asserted Patents teach "what it is about the claimed invention that provides the claimed function" of "not significantly block[ing]" fluid flow from the trabecular meshwork—specifically, the support props open Schlemm's canal while having minimal contact with the walls of the canal, particularly the portions interfacing with the trabecular meshwork and collector channels. The specification teaches that these are "common characteristic[s]" of devices for satisfying the Block Limitation. (*E.g.*, '443, 10:61-65, 11:30-38; *see also* Ex. 90 (Downs Reb.) ¶¶1082-1093.)

- 3. The Figures (and associated disclosures) of the Asserted Patents show various devices that prop open Schlemm's canal while minimizing contact with the walls of the canal, particularly the portions interfacing with the trabecular meshwork and collector channels. (*See, e.g.*, '443, 7:22-13:9, Figs. 5B-12H; Ex. 90 (Downs Reb.) ¶1082-1091; Ex. 93 (Downs 9/28 Tr.) 130:14-132:4.)
- 4. Determining whether a device satisfies the Block Limitation does not require a POSA to undertake extensive experimentation, does not require testing all potential supports, and does not require "painstaking experimentation." Rather, the amount of modeling or testing required, if any, (which a POSA would appreciate depends on the design) was routine. (Ex. 93 (Downs 9/28 Tr.) 37:11-21, 67:9-15, 71:8-72:9, 73:9-74:11, 77:19-78:14, 95:6-16, 103:5-15, 112:22-114:2, 116:15-117:5, 117:17-24, 130:14-132:4; Ex. 90 (Downs Reb.) ¶¶168-171, 1097-1102.)
- 5. Sight's expert Dr. Crawford Downs testified that a POSA would appreciate that some devices require no experimentation or modeling. (Ex. 93 (Downs 9/28 Tr.) 37:11-21, 85:16-87:19, 95:6-16, 130:14-132:4; Ex. 90 (Downs Reb.) ¶¶1084-1085.) He did not admit that "testing or modeling is required to determine whether a support has the claimed functionality."
- 6. Defendants themselves contend that a POSA would recognize that structures designed to minimize a support's contact with the walls of Schlemm's canal act to facilitate and not significantly block flow. (*E.g.*, Ex. 87 ('443 IPR Pet.) 30, 39-41, 50; Ex. 88 ('443 IPR Reynard Decl.) ¶¶69-71, 92-93; Ex. 89 (Tanna Op.) ¶¶141, 150, 153-154, 157, 239, 443.) Defendants contend that no experimentation was required to determine that such devices do not block flow. (*Id.*)
 - 7. The field of the invention is the mechanical arts, involving structures for facilitating

fluid flow in the eye. A POSA with engineering training, having knowledge and experience with fluid mechanics and the design of intraocular implants, would have appreciated that the structural features taught by the Asserted Patents would lead to predictable, testable effects on flow, based on understood scientific principles. (See Ex. 90 (Downs Reb.) ¶¶168-171, 1074-1081; see also, e.g., Ex. 93 (Downs 9/28 Tr.) 69:3-20, 86:2-87:8; Ex. 99 (Downs 9/22 Tr.) 225:8-227:23, 228:12-14, 286:3-12; Ex. 91 (IVANTIS SS 00454336) at 454350-61 ("These basic principles and 92 formulas have been used to study aqueous outflow for decades."); (IVANTIS SS 00172874) at 172932-33.)

- 8. The inventors did not fail to make a functional prototype. They were delayed in making a prototype due to lack of funding. (Ex. 86 (P. Badawi 6/23 Tr.) 108:15-109:4, 109:22-110:7.) Through personal funding and initial investments in their startup company, they were able to make and test an embodiment of the invention they called "Helix" in a cadaver eye perfusion study (*id.*, 110:8-23, 133:18-134:8.) That testing (conducted at the Mayo Clinic in 2010) affirmed that the devices facilitated and did not block fluid outflow and successfully reduced intraocular pressure (IOP) in glaucomatous eyes having a higher starting IOP. (Ex. 90 (Downs Reb.) ¶1079; Ex. 86 (P. Badawi 6/23 Tr.) 148:9-16; Ex. 94 (SGHT0161700) at 161701-03.)
- 9. Whether a device facilitated and did not block flow could be determined through analytical or computational models, the use of which was routine and within the skill of a POSA. (Ex. 93 (Downs 9/28 Tr.) 64:10-65:7, 67:9-15, 69:3-71:4, 71:8-74:11, 77:19-78:14, 79:11-21, 80:8-81:25, 82:13-85:3, 98:10-100:11; Ex. 90 (Downs Reb.) ¶¶168-171, 1068-1069, 1074-1077, 1099.)
- 10. A POSA understood that cadaver eye experiments could determine whether a device substantially interfered with flow. (Ex. 93 (Downs 9/28 Tr.) 77:19-78:14, 98:10-100:11,

- 103:5-15, 108:18-109:12; Ex. 90 (Downs Reb.) ¶¶1068-1069, 1071-1072, 1078, 1099; Ex. 60 (Bahler); Ex. 101 (Tanna 12/15 Tr.) 161:22-162:8, 163:13-21.)
- 11. A POSA recognized that cadaver eye experiments closely mimic *in vivo* conditions. Such experiments were routine. (Ex. 93 (Downs 9/28 Tr.) 103:19-104:11, 111:18-114:17, 115:7-12, 116:15-117:5, 117:17-24; Ex. 90 (Downs Reb.) ¶1072; Ex. 100 (Downs Reply) ¶¶56, 63.)
- 12. A POSA understood that fluorescent dye studies were routine to visualize flow of aqueous humor through the trabecular meshwork and Schlemm's canal. (Ex. 93 (Downs 9/28 Tr.) 12:15-24, 113:12-114:2; Ex. 102 (Downs 9/28 Tr. Ex. 5); Ex. 90 (Downs Reb.) ¶168.)
- Defendants understood and used terms like the Block Limitation in describing how the Hydrus device facilitates (and does not block) flow from the trabecular meshwork and into Schlemm's canal. For example, Defendants' documents show: Hydrus' windows allow fluid to exit through the trabecular meshwork. (*See* Ex. 21 (IVANTIS_SS_00415663) at 415712, 415721; Ex. 9 (Kimball Tr.) 94:21-23; Ex. 22 (IVANTIS_SS_00006997) at 7001 ("Hydrus Microstent also has 3 large windows that face the trabecular meshwork to allow aqueous to easily pass through the trabecular meshwork into Schlemm's canal."); Ex. 23 (IVANTIS_SS_00276222) at 276226; Ex. 97 (Downs Op.) ¶87-89, 91, 95-96; Ex. 100 (Downs Reply) ¶45-49, 51-52, 62.)
- 14. Ivantis represented to the FDA that windows of the Hydrus were designed to and did enable flow from the trabecular meshwork into Schlemm's canal. (Ex. 24 (IVANTIS_SS_00074707) at 74723 ("

"); see also Ex. 25 (IVANTIS_SS_00023750) at 23768; Ex. 97 (Downs Op.) ¶¶87-88, 91; Ex. 100 (Downs Reply) ¶49.)

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ Melanie K. Sharp

Melanie K. Sharp (No. 2501)
James L. Higgins (No. 5021)
Taylor E. Hallowell (No. 6815)
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
msharp@ycst.com
jhiggins@ycst.com
thallowell@ycst.com

COOLEY LLP Michelle S. Rhyu Jeffrey Karr Lauren Strosnick Alissa Wood Juan Pablo González Angela R. Madrigal 3175 Hanover Street Palo Alto, CA 94304-1130 (650) 843-5000

Orion Armon 1144 15th Street, Suite 2300 Denver, CO 80202-2686 (720) 566-4000

Dustin M. Knight Joseph Van Tassel Reston Town Center 11951 Freedom Drive, 14th Floor Reston, VA 20190-5656 (703) 456-8000

Bonnie Fletcher Price 1299 Pennsylvania Avenue, NW Suite 700 Washington, DC 20004-2400 (202) 842-7800

Attorneys for Sight Sciences, Inc.

Dated: November 2, 2023

30935499.1

CERTIFICATE OF SERVICE

I, Melanie K. Sharp, Esquire, hereby certify that on November 2, 2023, I caused to be electronically filed a true and correct copy of Concise Statement of Additional Facts in Support of Sight Sciences, Inc.'s Opposition to Defendants' Motion for Summary Judgment No. 1 of Invalidity for Lack of Enablement with the Clerk of the Court using CM/ECF, which will send notification to the following counsel of record:

John W. Shaw
Karen E. Keller
Andrew E. Russell
Nathan R. Hoeschen
Shaw Keller LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
jshaw@shawkeller.com
kkeller@shawkeller.com
arussell@shawkeller.com
nhoeschen@shawkeller.com

I further certify that on November 2, 2023, I caused a copy of the foregoing document to be served on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

BY E-MAIL:

Gregg LoCascio
Sean M. McEldowney
W. Todd Baker
Justin Bova
Steven Dirks
Socrates L. Boutsikaris
Kirkland & Ellis LLP
1301 Pennsylvania Avenue, N.W.
Washington, DC 20004
gregg.locascio@kirkland.com
sean.mceldowney@kirkland.com
justin.bova@kirkland.com
steven.dirks@kirkland.com
socrates.boutsikaris@kirkland.com

Jeanne M. Heffernan
Kat Li
Austin C. Teng
Ryan J. Melde
Lydia B. Cash
Kirkland & Ellis LLP
401 Congress Avenue
Austin, TX 78701
jheffernan@kirkland.com
kat.li@kirkland.com
austin.teng@kirkland.com
ryan.melde@kirkland.com
lydia.cash@kirkland.com

Ryan Kane
Nathaniel DeLucia
Laura Zhu
Emily C. Sheffield
Kirkland & Ellis LLP
601 Lexington Avenue
New York, NY 10022
ryan.kane@kirkland.com
nathaniel.delucia@kirkland.com
laura.zhu@kirkland.com
emily.sheffield@kirkland.com

Brian A. Verbus Jacob Rambeau 300 N. LaSalle Chicago, IL 60654 brian.verbus@kirkland.com jake.rambeau@kirkland.com

Noah S. Frank 200 Clarendon Street Boston, MA 02116 noah.frank@kirkland.com

/s/ Melanie K. Sharp
Melanie K. Sharp (No. 2501)

30935556.1